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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/539,032	03/30/2000	Samir Kumar Brahmachari	07064-01001	7985

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/539,032

Applicant(s)

BRAHMACHARI ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The rejections made under 35 USC 112, not reiterated below, are hereby withdrawn in view of the claim amendments filed 5/6/05. Applicant's arguments with regard to the lack of enablement are moot in view of the claim amendments and subsequent withdrawal of the rejection.

Specification

The amendment filed 9/10/04 is again objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a step of providing electronic data representing peptide libraries for selected organisms, as set forth on amended page 7 of the specification, is new. The originally filed specification and original claim 1 recited a step of computationally generating overlapping peptide libraries for selected organisms. A step of computing and/or generating overlapping libraries is different from a step of merely providing a library. It is noted that as the originally filed step recited actual computation/generation, the library of the original step would be expected to be different from that found in a pre-existing database, thus neither the step nor the resulting library is supported by the originally filed disclosure.

Applicant's arguments filed 5/6/05 have been fully considered but they are not persuasive. Applicant amended claim 1, but did not amend the specification to overcome the objection. In response to the argument that the originally filed specification and claims teaches the use of a library creation program, the examiner

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maintains that a step of *generating* a peptide library is not the same as providing such a library, as a step of providing encompasses provision of a pre-existing library. As the newly taught step is broader than that originally disclosed, the examiner maintains that the amendment to page 7 filed 9/10/04 introduced new matter, and the objection is maintained.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 1 is objected to because of the following informalities: the phrase "generating computationally" as recited in amended step (i) of claim 1 is grammatically awkward. The examiner recommends --computationally generating-- for better clarity. Appropriate correction is requested.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A step of identifying "conserved sequences" not present in a host organism using method steps (i)-(vi), as recited in claim 1, is new matter. As all previous steps of claim 1 are directed to peptide sequences, the newly recited "conserved sequences" of step amended step (vii) are interpreted to be peptide sequences. Original claim 1 recited comparison of genomes to identify sequences not commonly conserved between pathogenic versus non-pathogenic strains, and searching for given "conserved sequences" in a host genome and rejecting those not present in the host genome. The original claim steps are clearly directed to comparison of nucleic acid sequences (i.e. genomic material); the original claims did not recite identification of any peptide sequences not present in a host genome. In the response filed 5/6/05, applicant points to page 16, Example 7 for support for the new step. In response, it is noted that Example 7 states that DNA gyrase is a KNOWN protein which is absent in humans, and that various invariant peptides from DNA gyrase COULD BE used as potential drug targets. It is noted that the peptides of Example 7 are selected from a protein previously known to be absent in humans. ANY peptide, conserved or not, from DNA gyrase, would be reasonably expected to be one "not present" in humans (i.e. a host organism). There is no disclosure anywhere for a step of "identifying" any conserved sequences/peptides not present in a host organism. Steps (i)-(vi) of claim 1 are merely directed to identification of conserved peptides. The specification indicates that these steps may be used variously to identify peptides conserved across several species of microorganism (p. 14, Example 2) or to assign function to proteins with previously unknown activity (p. 15, Examples 5 and 6). The "identification" in Example

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7 merely suggests that conserved peptides from a protein KNOWN to be absent in humans are possible binding sites/drug targets, but does not specifically identify those peptides as those not present in a host organism based on recited steps (i)-(vi). As neither the originally filed specification or claims provide support for new step (vii), claim 1 recites new matter. Claims 2-9 depend from claim 1 and therefore also recite new matter.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a step (vii) of identifying conserved sequences not present in a host organism. The relationship between step (vii) and previous steps is unclear, therefore claim 1 is indefinite. Steps (v) and (vi) recite obtaining and annotating secondary structure of "extended conserved peptide sequences". It is unclear whether the "extended conserved peptide sequences" of steps (v) and (vi) are intended to be the same as the "conserved sequences" identified in new step (vii). Further, it is unclear what relationship is intended, if any, between the structural annotation of step (vi), and the identification of step (vii).

Claims 2-9 depend from claim 1 and are therefore also indefinite.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
7/11/05